

**LIBELED:** 8-21-61, 8-29-61, and 8-30-61, Dist. Mass.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it purported to possess; 502(a)—the label statement "4-nitrophenyl-arsonic acid (Histostat) 0.025%" was false and misleading as applied to a product which contained more than the declared amount of this ingredient; and 502(j)—the article was dangerous to the health of turkeys when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling.

**DISPOSITION:** 2-16-62. Consent—claimed by Elmore Milling Co., Inc., and released under bond to be brought into compliance with the law.

## NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

### DRUGS FOR HUMAN USE

**6904. Vitamin B<sub>12</sub>-B<sub>1</sub>, Elixir Vinivita, and Expectogen.** (F.D.C. No. 46942. S. Nos. 37-804/6 T.)

**QUANTITY:** 16 btl. of *Vitamin B<sub>12</sub>-B<sub>1</sub>*, 151 1-pt. btl. of *Elixir Vinivita*, and 203 1-pt. btl. of *Expectogen*, at Montgomery, Ala.

**SHIPPED:** Between 2-27-61 and 9-26-61, from St. Louis, Mo., by E. W. Heun Co.

**LABEL IN PART:** (Btl.) "Vitamin B<sub>12</sub>-B<sub>1</sub> Each 5 cc. (1 teaspoonful) contains: Vitamin B-12, N.F. 25 mcg. Vitamin B-1 U.S.P. 10 mg. Manufactured for King Pharmaceutical Co., Inc., Montgomery 3, Alabama."; "King's One Pint Elixir Vinivita Improved Each 5 cc. (1 teaspoonful) contains: \* \* \* Distributed by King Pharmaceutical Co., Inc., Montgomery, Alabama \* \* \* Caution: Federal law prohibits dispensing without a prescription."; and "King's One Pint Expectogen For Relief of Coughs Due to Colds Each Fluid Ounce Represents: Dextromethorphan Hydrobromide 60 mg. Chlorpheniramine Maleate 12 mg. Potassium Guaiaccol Sulfonate 8 gr. Ammonium Chloride 8 gr. Tartar Emetic 1/12 gr. Chloroform 2 min. \* \* \* Distributed by King Pharmaceutical Co., Inc., Montgomery, Alabama. Dosage: Adults, orally 1 or 2 teaspoonsful every four hours as required. Children 6-12 years, one-half adult dose. For younger children consult physician."

**LIBELED:** 1-29-62, M. Dist. Ala.

**CHARGE:** (*Vitamin B<sub>12</sub>-B<sub>1</sub>*), 502(a)—when shipped, the bottle label contained false and misleading representations that the article was adequate and effective for promoting growth and appetite in a child who does not eat adequately or well; as an adjunct in treating the chronically ill or undernourished child; as a nutritional supplement in chronic diarrhea and celiac diseases; and for shortening convalescence through increasing the appetite; (*Elixir Vinivita*), 502(a)—the bottle label contained false and misleading representations that the article was adequate and effective as a treatment for or preventive of chronic fatigue, poor appetite, and iron and vitamin deficiencies; 503(b)(4)—the article was not subject to the provisions of 503(b)(1) and its label bore the statement "Caution: Federal law prohibits dispensing without prescription"; and (*Expectogen*), 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

**DISPOSITION:** 2-2-62. Consent—destruction.